



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection

techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Kelly Yu, PhD, Division of Cancer Prevention, 9609 Medical Center Drive, Room 5E230, Rockville, MD 20850 or call non-toll-free number 240-276-7041 or E-mail your request, including your address to: yuke@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO), 0925-0407, Extension, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a request for a revision of the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO). This trial was designed to determine if cancer screening for prostate, lung, colorectal, and ovarian cancer can reduce mortality from these cancers which caused an estimated 253,320 deaths in the U.S in 2014. The design is a two-armed randomized trial of men and women aged 55 to 74 at entry. OMB first approved this study in 1993 and has approved it every 3 years since then. Recruitment was completed in 2001, baseline cancer screening was completed in

2006, and data collection continues on the current cohort of 77,281 participants who are actively being followed. The additional follow-up will provide data that will clarify further the long term effects of the screening on cancer incidence and mortality for the four targeted cancers. Further, demographic and risk factor information may be used to analyze the differential effectiveness of cancer screening in high versus low risk individuals.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 26,320.

Estimated Annualized Burden Hours

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (Minutes/Hour)	Annual Burden Hours
Annual Study Update(ASU) Form	Participants who complete the ASU	77,281	1	5/60	6,440
ASU Telephone Script	Non Responders to the ASU	3,091	1	5/60	258
Authorization to Release Medical Records	Participants who report new cancers	2,700	1	3/60	135
Health Status Questionnaire (Female) (HSQ)	Female participants who complete the HSQ	960	1	5/60	87
Health Status Questionnaire (Male) (HSQ)	Male participants who complete the HSQ	1,040	1	5/60	80
Medication Use Questionnaire (MUQ)	Participants who complete the MUQ	77,281	1	15/60	19,320

Dated: April 7, 2015.

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